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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/628,141 | 07/24/2003 | Srinivas G. Rao | CYPR 101 | 5413 |
| 7278 | 7590 | 12/06/2005 | EXAMINER | |
| DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257 | | | | COOK, REBECCA |
| | | ART UNIT | | PAPER NUMBER |
| | | 1614 | | |

DATE MAILED: 12/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 10/628,141 | Applicant(s) RAO ET AL. |
|-------------------------------------|--|---------------------------------------|
| Examiner Rebecca Cook | Art Unit 1614 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 12 September 2005.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-18 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-18 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/21/03, 3/1/05
4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ .
5) Notice of Informal Patent Application (PTO-152)
6) Other: ____ .

DETAILED ACTION

Election/Restrictions

Applicants elected the NSRI milnacipran. Claims 1-18 read on milnacipran and are examined.

Priority

No support is seen in parent applications 10/028,547, filed December 19, 2001 or parent application 10/014,149, filed November 15, 2001 for the claimed "method of treating or preventing atypical depression secondary to pain (DSP).

Information Disclosure Statement

Information Disclosure Statements filed November 21, 2003 and March 1, 2005 are acknowledged and have been reviewed. All submissions fail to comply with 37 CFR 1.98(a)(3) because they do not include a concise explanation of the relevance of each document.

Applicant has an obligation to call the most pertinent prior art to the attention of the Patent Office in proper fashion. Burying one reference in dozens of other IDS references amounts to citing nothing. *Pen Yan Boats, Inc. v. Sea Lark Boats, Inc.*, 37 USPQ 260 (DC Fla 1972). *Golden Valley Microwave Foods, Inc. v. Weaver Popcorn Co., Inc.*, 24 USPQ2d 1801 (U.S. Dist. N. Dist.)

The following references were not present in the file and could not be considered: Joyce, 2002 and Paykel, 1983.

Claim Objections

The claims are objected to as containing non-elected subject matter.

Claim Rejections - 35 USC § 112

Claims 4-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for any and all derivatives. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. It is not clear what compounds would be included in the term "derivatives," such as compounds including heterocyclic moieties, sulfonamide moieties, nitroso moieties, etc and it would take undue experimentation to determine which derivatives would yield the active compound.

Claims 4-6 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 4 the recitation "or sterioisomeric forms, mixtures of sterioisomeric forms, metabolites, derivatives, or pharmaceutically acceptable salts thereof" is confusing as to whether all of each sterioisomeric forms, mixtures of sterioisomeric forms, metabolites, derivatives, or pharmaceutically acceptable salts are required. Amending the recitation to recite "or a sterioisomeric form, mixtures of sterioisomeric forms, metabolite, derivative, or pharmaceutically acceptable salt" will overcome this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by 4,478,846. '836 discloses (columns 1-2 and 11) milnacipran and its formulation. It discloses formulations that deliver a dosage greater than the dosage required to treat typical depression. It does not disclose that it is suitable to treat atypical depression. However, intended use does not impart patentability to a composition claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over 4,478,846 (Mouzin) in view of 5,942,549 (Vargas). Mouzin discloses (columns 1-2 and 11) milnacipran, its dosage, and that it is used to treat depression. Vargas et al (column 1, lines 15-35) disclose sibutramine and that it is used to treat depression. “[I]t is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose...[T]he idea of combining them flows logically from their having been individually taught in the prior art.” *In re Kerkhoven* 105 USPQ 1069. Therefore, in the absence of a showing of unexpected results, it would be obvious to one of ordinary skill

to combine milnacipran and sibutramine to yield the instant composition, since each is individually taught in the prior art to be useful to treat depression.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over 4,478,836 (Mouzin et al) in view of Dworkin et al or Ruoff et al and Quitkin et al. Mouzin et al (abstract) disclose the milnacipran and that it can be used to treat depression. The instant claims differ over Mouzin et al in reciting treating or preventing DSP. However, Quitkin et al disclose atypical depression is a distinct subgroup of depression that is otherwise indistinguishable from simple mood depression except for the presence of at least one vegetative atypical sign. They also disclose that both forms of depression respond to many of the same compounds. Additionally, Dworkin et al and Ruoff et al each disclose that chronic pain patients often have depressive disorders. In view of the teaching of Quitkin et al and Dworkin et al or Ruoff et al, it would be obvious to one of ordinary skill in the art to use milnacipran to treat DSP, since it responds to many of the same compounds that are used to treat simple mood depression.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davidson et al in view of Palmier et al and Dworkin et al or Ruoff et al.

Davidson et al (abstract) discloses that monoamine oxidase inhibitors (MAOI) are effective in treating DSP. Davidson et al do not disclose using milnacipran or treating DSP associated with pain. However, Palmier et al (summary) disclose that milnacipran is an MAOI. Additionally, Dworkin et al and Ruoff et al each disclose that chronic pain patients often have depressive disorders. In view of the teaching of Palmier et al and Dworkin et al or Ruoff et al it would be obvious to use milnacipran to treat DSP,

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Jones (571) 272-0547 in Customer Service.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The official fax number is 571-273-8300.

Rebecca Cook



Rebecca Cook
Primary Examiner
Art Unit 1614

December 3, 2005